# DeviceSafety

## Safeguarding contrast media injections

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A 62-YEAR-OLD MAN came to the ED complaining of midsternal pain, shortness of breath, diaphoresis, and nausea after shoveling snow. A diagnostic cardiac catheterization indicated arterial blockage, and the patient underwent angioplasty without incident. Afterward, a venogram was performed to evaluate left ventricular function. During the procedure, the patient experienced cardiac arrest and died.

**What went wrong?**

This event was directly attributed to error by medical personnel. The biomedical engineering department at the facility evaluated the contrast medium injector device involved in the event and found no malfunctions that could have been responsible. The manufacturer performed a failure analysis and concurred.

Further investigation revealed that the disposable syringe used during the venogram wasn't filled with contrast medium beforehand. At least 30 cc of air was injected directly into the patient's left ventricle, causing an air embolism that led to cardiac arrest.

**What precautions can you take?**

- Carefully review all operators' instructions before using any invasive diagnostic equipment.
- Assign one person, if possible, to always be responsible for filling the contrast injector.
- Have a second person confirm appropriate filling of the injector and check it again just before the medium is injected.

If a death, serious injury, or malfunction involving a contrast medium injector occurs where you practice, notify the person at your facility who's responsible for reporting such problems or call MedWatch at 1-800-FDA-1088. To learn about the FDA Center for Devices and Radiological Health (CDRH), visit the homepage at **www.fda.gov/cdrh.**

Although you need to support the adverse event–reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Device Safety is coordinated by Beverly Gallauresi, RN, BS, MPH.